AUG 2 5 2000

K002157

510(k) Summary

Invacare Corporation's RANGER II M6

Submitter's Name, Address, Telephone Number, Contact Person:

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Invacare, Inc.
One Invacare Way
P.O. Box 4028
Elyria, OH 44036
Telephone: (440) 329-6000
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Date Prepared:

July 17, 2000

Name of Device and Name/Address of Sponsor:

RANGER II M6

Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, OH 44036
Telephone: (440) 329-6000
Facsimile: (440) 365-4558

Classification Name:

Powered Wheelchair

Common Name:

Motorized Wheelchair

Product Code:

ITI

Predicate Device:

Permobil Inc.'s Chairman

Intended Use

RANGER II M6 is intended to provide mobility to persons limited to a sitting position.

Substantial Equivalence

The RANGER II M6 is a powered wheelchair. The RANGER II M6 is indicated for use by disabled persons who weigh up to 250 pounds. The RANGER II M6 wheelchair consists of two basic sub-sections: (1) the base section and (2) the seating section. The base section includes: (1) the base frame; (2) mid drive wheels and axles; (3) front and rear pivoting casters; (4) motor/gearbox drive mechanism; and (5) two batteries. The seating section includes: (1) the seating upholstery; (2) front footrests; (3) side arm rests; and (4) joystick operating control. To use the RANGER II M6, the person is placed in a sitting position. The user then uses the proportional joystick to control the direction of the RANGER II M6.

The RANGER II M6 and the Chairman have the same intended use. In addition, these powered wheelchairs have similar principles of operation in that the user controls the direction of the device's movement by means of a joystick. Both devices also have similar technological characteristics. Although there are some differences in their technological characteristics, namely the RANGER II M6's number of swivel wheels, drive wheel position, parking brake system, dimensions, and weight. These technological differences do not raise any new issues of safety or effectiveness. Moreover, the device complies with applicable sections of ANSI/RESNA standards regarding wheelchairs, ISO 7176 and IEC 60601.

Therefore, the RANGER II M6 is substantially equivalent to the Chairman for providing mobility to persons limited to a sitting position.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2000

Invacare Corporation
c/o Mr. Howard M. Holstein
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K002157
Trade Name: Ranger II M6 Powered Wheelchair, Model IN-888WNL
Regulatory Class: II
Product Code: ITI
Dated: July 17, 2000
Received: July 17, 2000

Dear Mr. Holstein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K

Device Name: RANGER II M6

Indications for Use: The RANGER II M6 power wheelchair is intended to provide mobility to persons limited to a sitting position. The device is indicated for persons who weigh no more than 250 lbs.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

NOD for CMW

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002157

Prescription Use ____ OR Over-The-Counter Use X
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)